Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.

Medical Countermeasure Systems (MCS)

COL Russell E. Coleman
Joint Project Manager
Medical Countermeasure Systems
russell.e.coleman.mil@mail.mil

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MCS
MEDICAL COUNTERMEASURE SYSTEMS

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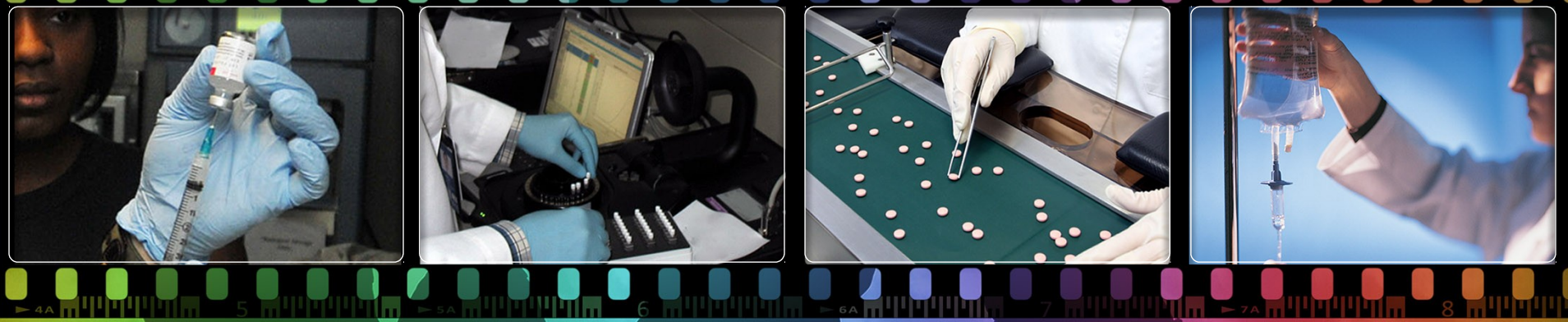
Medical Countermeasure Systems (MCS)

- **VISION** A U.S. military force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide

- **MISSION** To provide U.S. military forces and the nation safe, effective, and innovative medical solutions to counter CBRN threats

Spectrum of Medical Countermeasures (MCM)



PREVENTION

PROPHYLAXIS SUSTAINS THE FORCE

DIAGNOSIS

DIAGNOSTIC IDENTIFIES THREATS TO TREAT

TREATMENT

THERAPEUTIC SAVES LIVES

MCS Organizational Structure

JPM-MCS

Joint Project Manager-Medical Countermeasure Systems Project Management Office

Special Staff

- Contracting Team
- Legal Advisor
- Strategic Initiatives

Special Staff

- Chief Medical
- Chief Technical

Joint Product Managers (JPdMs)

- Joint Vaccine Acquisition Program
- Diagnostics Program
- Chemical Defense Pharmaceuticals
- Biological Defense Therapeutics

Product Support Offices

- Development Manufacturing Capability
- Critical Reagents Program

Functional Directorates

- Medical Acquisition
- Business & Finance
- Medical Logistics
- Management Support
- Medical Regulatory

MCS-Diagnostics

Mission

Develop, acquire, integrate, and field identification technologies and FDA-cleared diagnostic devices intended for Service Members to aid in the early diagnosis, prevention, and treatment of the effects of exposure to chemical, biological, and radiological (CBR) agents

MCS-Diagnostics

- **Current products and programs**
  - Joint Biological Agent Identification and Diagnostic System (JBAIDS) lifecycle management: Fielded
  - Joint Handheld Biological Identifier (JHBI)
  - Next Generation Diagnostics System (NGDS) Increment 1: MS C FY16
  - NGDS Increment 2: Preparation for milestone (MS) B FY16

MCS-Diagnostics

Fielded / FDA Approved Product

FDA APPROVED

FIELDED Joint Biological Agent Identification and Diagnostic System (JBAIDS)

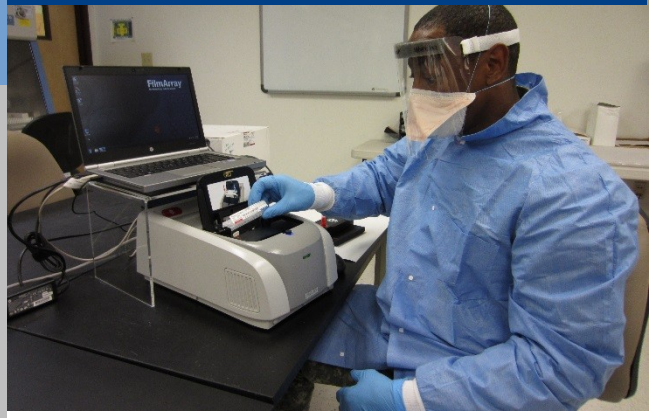
Ruggedized mobile laboratory analytical system that provides rapid and highly accurate identification of multiple biological agents in clinical, food, and environmental samples.

- Anthrax Assay
- Plague Assay
- Tularemia Assay
- H5N1 Avian Flu Assay
- Q-Fever Assay
- Influenza A&B Typing Assay
- Influenza A Subtype Assay
- Ebola Zaire (EZ1) rRT-PCR EUA

- Surveillance Assays:
  - *Bacillus anthracis*
  - *Yersinia pestis*
  - *Coxiella burnetii*
  - *Francisella tularensis*
  - *Brucella spp.*
  - *Burkholderia mallei/B. psuedomallei*
  - Eastern Equine Encephalitis
  - Marburg
  - *Rickettsia prowazekii*
  - Variola (smallpox)
  - Orthopox
  - Venezuelan Equine Encephalitis
  - Western Equine Encephalitis
  - Ebola (Zaire)
  - Campylobacter
  - Salmonella
  - Listeria

FIELDED GDS) Increment 1

platform for multiple biological threat agents. Automated system will be integrated across all levels of the military health system. Deployed in response to West Africa Ebola outbreak (EUA).



- Ebola Assay (EUA)
- Fielded 40 FilmArray 1.5v systems and 3800 tests in support of Operation United Assistance

MCS-Diagnostics

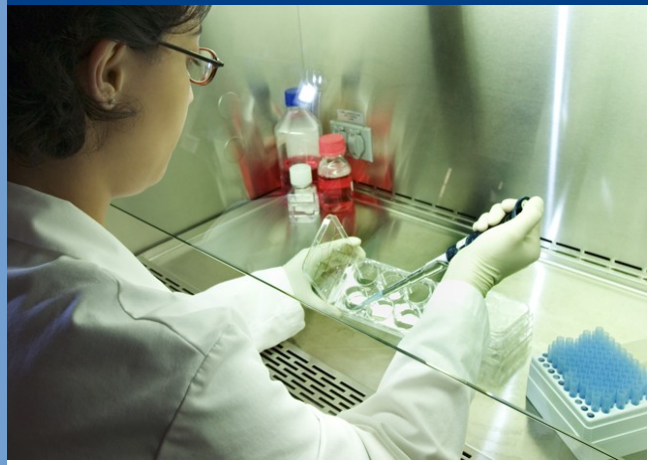
Advanced Development Products

Next Generation Diagnostics System (NGDS) Increment 1

Description	Common medical test equipment and diagnostic platform for multiple biological threat agents, automated and integrated across all levels of the military health system
Last Milestone	MS A, Feb 2012
Clinical / FDA Accomplishment DoD FDA	▪ N/A
Next Steps	➟**Next Acquisition MS:** MS C, 4QFY16 ➟**Next Clinical MS:** 4QFY16 ➟**Projected FDA Clearance Date:** 4QFY16

GDS) Increment 2

Last Milestone	MDD
Clinical / FDA Accomplishment DoD FDA	▪ N/A
Next Steps	➟**Next Acquisition MS:** MS B 2QFY16 ➟**Next Clinical MS:** N/A



Milestone = MS

MCS-Diagnostics

Advanced Development Products

Joint Hand-held Biological Identifier Increment 1

Description	Provide the capability to rapidly and accurately identify bio-agents at the point of contact from environmental samples with a handheld device
Last Milestone	MS B, Mar 2015
Clinical / FDA Accomplishment	DoD FDA ▪ NA
Next Steps	➟**Next Acquisition MS:** MS C, FY16 ➟**Next Clinical MS:** N/A; environmental identifier ➟**Projected FDA Clearance Date:** NA

Milestone = MS

Tenants of NGDS Inc 2

- **Expand the breadth and depth of CBRN diagnostics**
  - Breadth: Diseases for which PCR is not an effective diagnostic test method
  - Depth: Fast, Easy and Lightweight materiel solutions that would be operationally suitable for use at any echelon of care, when supported by other DOTMLPF elements
- **Maximally integrate with endemic infectious disease diagnostics and routine health care to achieve affordability, supportability and clinical utility**
- **Select the simplest *effective* solution for each disease**
  - Single use disposable tests (e.g. Lateral Flow Immunoassays)
  - Augmentation of existing fielded medical devices – assays and COE
  - New instrument development
- **Seek Interim Fielding Capabilities (IFC): Pre-Emergency Use Authorization**
- **Complementary to NGDS Inc 1 (FilmArray)**
  - Diseases selected for development on Inc 2 devices in context of Inc 1

NGDS Inc 2 Acquisition Approaches / Potential JE-RDAP Opportunities

- **NGDS Increment 2 proposes to provide up to 4 independent materiel solutions to deliver diagnostic capability sets to the Warfighter**
  1) Lateral Flow Immunoassay (LFI) *in vitro* diagnostics (IVD)
  2) IFC: Pre-EUA for BWA assays on existing fielded system (Abbott I-Stat)
  3) Advanced PCR for Diagnostics
     - Must have significant advancements beyond FilmArray in speed, size, weight, power and cost per test
     - Dependent upon emergence of requirement and concept of employment that would necessitate a second molecular diagnostic materiel solution within the NGDS
     - Materiel Solution Analysis underway to inform acquisition strategy
  4) Multiplexed Device (i.e. affinity technologies)
     - CLIA waived, sensitive, multiplexed, expandable
     - Anticipated to be used side by side with FilmArray / other molecular diagnostic
     - Intended to be forward compatible to next gen host response biomarker based assays – difficult pathogens, toxins, chemical, NTA and rad

Contact Us

Jennifer Dabisch
Acting, Joint Product Manager
Diagnostics (Dx)
Medical Countermeasure Systems (MCS)
Office: 301.619.4434 | Blackberry: 301.693.1382
Email: jennifer.c.dabisch.civ@mail.mil

Jason Opdyke , Ph.D.
Senior Scientist
Diagnostics (Dx)
Contractor Support, Tauri Group
Medical Countermeasure Systems (MCS)
Office: 301.619.2881 | Blackberry: 240.409.7747
Email: jason.a.opdyke.civ@mail.mil

edical Countermeasure Systems (MCS) Project Management Offices

MCS-Fort Detrick (HQ)
1564 Freedman Drive
Fort Detrick, MD 21702-5041
301-619-7400

MCS-Frederick Annex
1110 Thomas Johnson Drive, Ste 240
Frederick, MD 21702-5041